

Docket No. M-1107 US

Response to Final Office Action**Overview**

5 Applicant is referring to Lantz, U.S. Patent Publication Number 2006/0120432 A1 by paragraph number when responding as Applicant. Canfield, U.S. Patent 6, 196, 959, is referred to as Canfield. Makita, U.S. Patent 5, 340, 215, is referred to as Makita. Yamaka, U.S. Patent 6, 367, 973 is referred to as Yamaka. The Applicant is again submitting its Jinga Affidavit that is directed to the need for a sanitary probe tip. The
10 Applicant amended claim 1 in response to the 103 rejections.

With this amendment, the Applicant has filed an RCE and is requesting the Examiner accept the RCE to review the Applicant's remarks and amendments.

Background

15 Applicant's invention claims at least one finger ejects the probe cover from the probe tip without exposing the ejecting finger to possible contamination from a patient's body part. In the prior art cited, the exterior surface of the probe tip and eject finger can become contaminated during use within a patient's ear, even with a protective cover. Possible contamination of the Applicant's ejection finger or probe shaft or tip is avoided
20 when the Applicant's cover shields the probe tip and ejection fingers, when the probe tip or shaft is inserted into the ear to take a temperature measurement.

As claimed, the Applicant's ejection finger moves distally toward a distal end of the probe tip, along the outer surface of the probe tip and along the inner surface of the

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probe cover. The cover conceals the ejection finger and probe tip up to an underside of the thermometer housing. The finger engages a proximal face at the inner surface of the probe cover as the finger moves distally along the probe tip to eject the probe cover.

5 **Claim Rejections – 35 U.S.C. § 103; Claims 1 & 4-12**

The Examiner rejects claims 1 and 4-12 under 35 U.S.C. § 103 as obvious over Yamaka in view of Canfield and further in view of Makita. This rejection is not proper. The cited references alone or in combination fail to teach or suggest all of the features of claim 1. As shown in the figures of Yamaka, and in particular FIG. 1, the probe cover 10 (10) does not cover the probe tip and supporting assembly up to the casing (21, 24). The cover (10) stops along the pushing member (70), leaving a portion of the pushing member (70) exposed to germ transfer. See Jinga Affidavit.

The Examiner has stated in part

15 "a probe 10 being mountable to the distal end of the tympanic thermometer 1, the mounted probe cover 10 defining an inner surface configured to engage the outer surface of the probe 6, and the mounted cover 10 conceals the finger 70 and the outer surface of the probe tip, the probe cover 10 including at least one proximal face projecting at the inner surface of the probe cover 10."

20 First, in the present invention its cover (32) is mounted to the distal end of the probe tip, as shown in FIG. 3. When mounted, the cover abuts up and provides a seal against the distal face (F) of the distal end (24) of the heat sensing probe (22), as annotated by the Applicant provided Exhibit I (4 pages). There is no space between the flange (64) of the probe cover (32) and the distal face (F), in the Applicant's invention. By contrast, there is a space shown at "S", in Yamaka FIG. 3, between the flange (17) of the Yamaka cover (10) and its casing (22), the exposed space "S" is along the

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pushing member (70). The Yamaka pushing member (70) is the same feature as the Applicant's eject fingers (28). Thus, no *prima facie* obviousness rejection may be stated against claim 1 and its dependent claims 4-12, because Yamaka, Canfield, and Makita, alone or in combination, fail to teach or suggest all of the features of claim 1, and in particular completely covering the exposed eject fingers (28). Furthermore, Yamaka may not be combined with Canfield and Makita in the manner proposed by the Examiner because the Examiner fails to state a sufficient reason to combine Yamaka with the other references under *KSR Int'l. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (U.S. Apr. 30, 2007).

The Examiner bears the burden of establishing a *prima facie* case of obviousness based on the prior art when he reject claims under 35 U.S.C. section 103. *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). Also, the cited references alone or in combination must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981 (CCPA 1974). In the present application, the limitation of the probe cover flange abutting to the underside of the thermometer housing is not disclose or taught in the cited references. Furthermore, Yamaka teaches away, thus, the Examiner has failed to make the necessary *prima facie* case of obviousness when the cited references, assuming there is motivation to combine, do not teach or suggest all of the features of the claimed invention.

Yamaka teaches away and thus provides no motivation to combined because Yamaka is concerned with maintaining a specific coverage, not complete coverage, of its pushing member (70) when "When the probe 6 covered with the probe cover (10) is inserted into the earhole, the stepped portion 13 abuts against the region in the vicinity

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of the entrance to the earhole so as to regulate the insertion depth of the probe 6 into the earhole at a predetermined depth. Therefore, the measuring error caused by the change in the insertion depth of the probe 6 into the earhole can be prevented so as to permit the body temperature to be measured under optimum conditions." Clearly,

5 Yamaka is directed to solving a different problem when it partially covers its pushing member (70) with its cover (10). There can be no suggestion, motivation or teaching to combine the references of using a probe cover (10), as claimed, to fully protect the Yamaka eject fingers (70) from contamination, when the cover (10) is designed to regulate the depth of insertion of the probe tip into the ear. The Yamaka FIG. 3,
10 reproduced at the Applicant's Exhibit I (at "S"), clearly illustrates the exposure along the pushing member (70) of Yamaka.

The Examiner fails to state sufficient reason to combine the cited references. As stated above, the Examiner bears the burden of establishing *prima facie* case of obviousness. In *Graham*, the scope and content of the prior art are ... determined; 15 differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the art is resolved. Often, it will become necessary for a court to look to interrelated teachings of multiple patents; the effects of the demands known to the design communicate or present in the market; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether
20 there was an apparent reason to combine the know elements in the fashion claimed by the patent application at issue. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (U.S. Apr. 30, 2007). The Examiner has provided no articulated reason supported by the teachings of the cited references, when the teachings of the cited references disclose

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the probe cover not completely covering the probe tip, as claimed. A major difference exists between the cited references, alone or in combination, and the claim 1 under the *Graham v. John Deere Co.* inquiry. The Examiner does not cite or discuss any reasoning for combination of the cited references. And the Applicant respectfully suggests, the Yamaka reference does not disclose completely covering its pushing member (70) or eject finger (28). Furthermore, Yamaka teaches away when its probe cover (10) does not cover the pushing member (70) completely to achieve a difference benefit of helping to prevent too deep of an insertion of the probe tip into the ear for improving accuracy of temperature measure. Yamaka is silent about cross contamination when the probe tip is exposed to human hair or excretions at the ear drum. See Jinga Affidavit.

At page 4-5 of the Office Action, the Examiner rejects claims 1, 7&9, based on Yamaka and Canfield. The Applicant respectfully suggests since there is no motivation to combine Yamaka with Canfield and, in fact, Yamaka teaches away (see col. 7, 15 53:67), from the claimed invention, the Examiner has not met his burden to establish a prima facie case of obviousness. The Applicant respectfully points out that the rejection on pages 4-5 does not address the point of novelty, which is covering the probe tip with the cover to prevent cross contamination. Thus, the Applicant suggests he has fully responded to the Office Action at pages 4-5. Claim 1 is allowable over the prior art of Yamaka and Canfield.

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Summary

The Applicant respectfully suggests claim 1, as amended, is allowable, and dependent claims 2-12 are also allowable. The Applicant respectfully requests the
5 Examiner accept his RCE submitted with this reply.

Applicant respectfully requests an Examiner interview, if the above amendments and the supporting Affidavits do not place this application in a condition of allowance. Applicant authorizes the Commissioner for Patents to charge Deposit Account number 19-0254 for any late fees or charges necessary to avoid abandonment. I can be
10 reached direct at (508) 261-8476 or Edward.jarmolowicz@tycohealthcare.com.

Respectfully yours,



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Attorney for the Applicant
Tyco Healthcare Group LP d/b/a/ Covidien
15 Hampshire Street
Mansfield, MA 02048

APPLICANT'S EXHIBIT I

1 of 4

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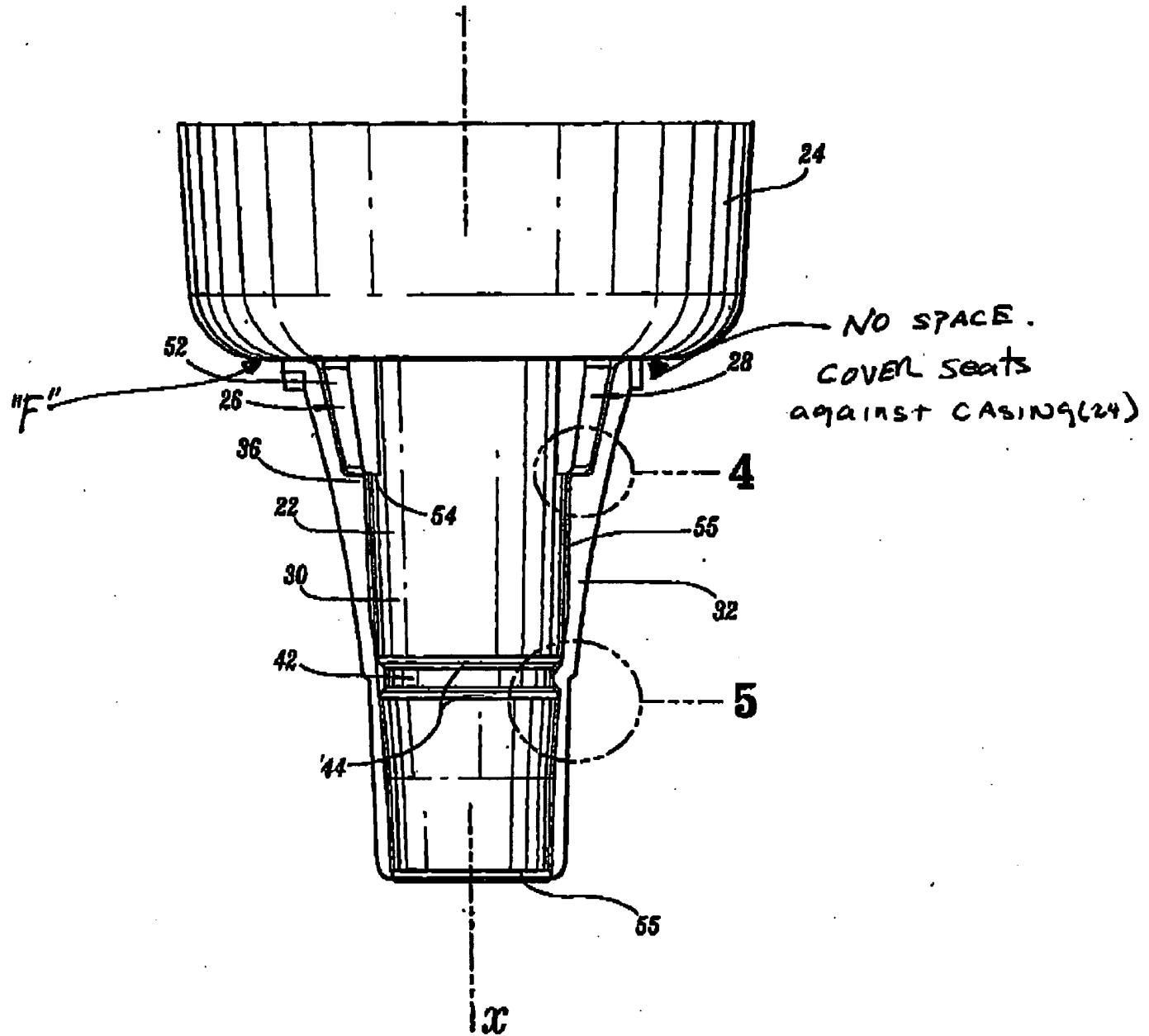


FIG. 3

APPLICANT'S EXHIBIT I 204

U.S. Patent

Apr. 9, 2002

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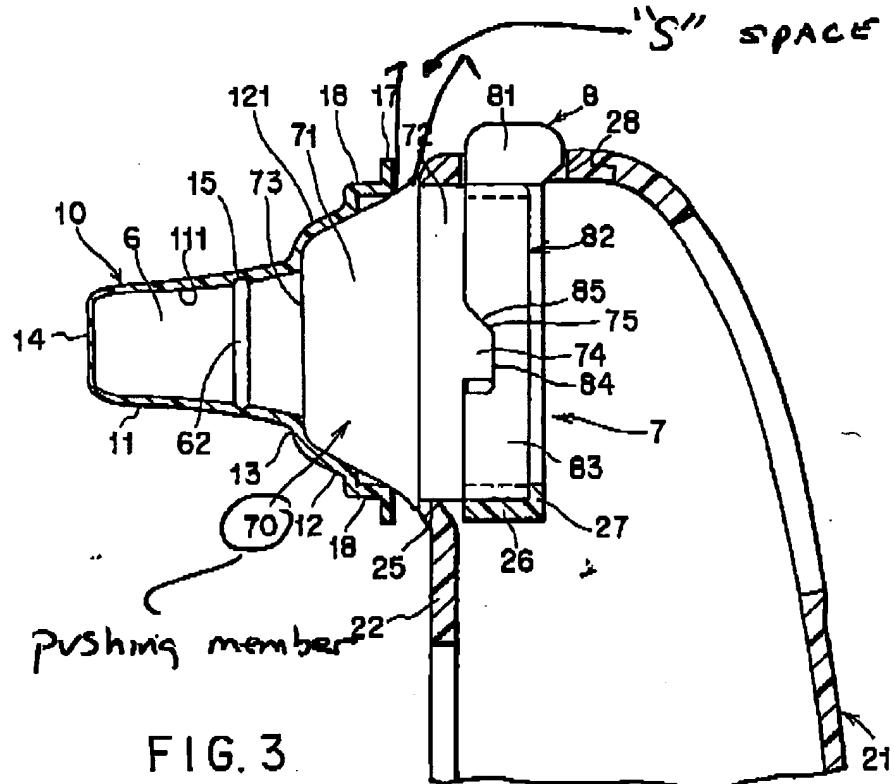


FIG. 3

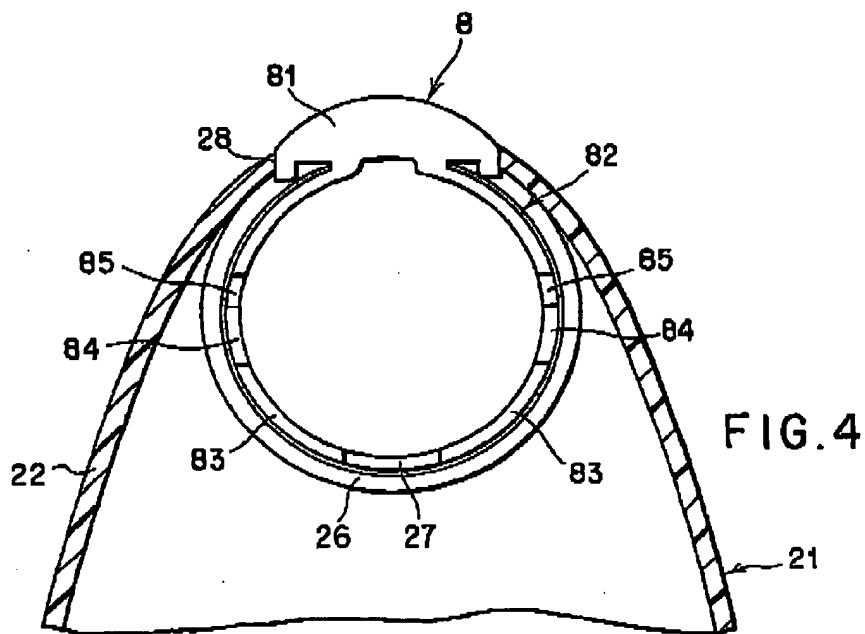


FIG. 4

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Feb. 13, 2001

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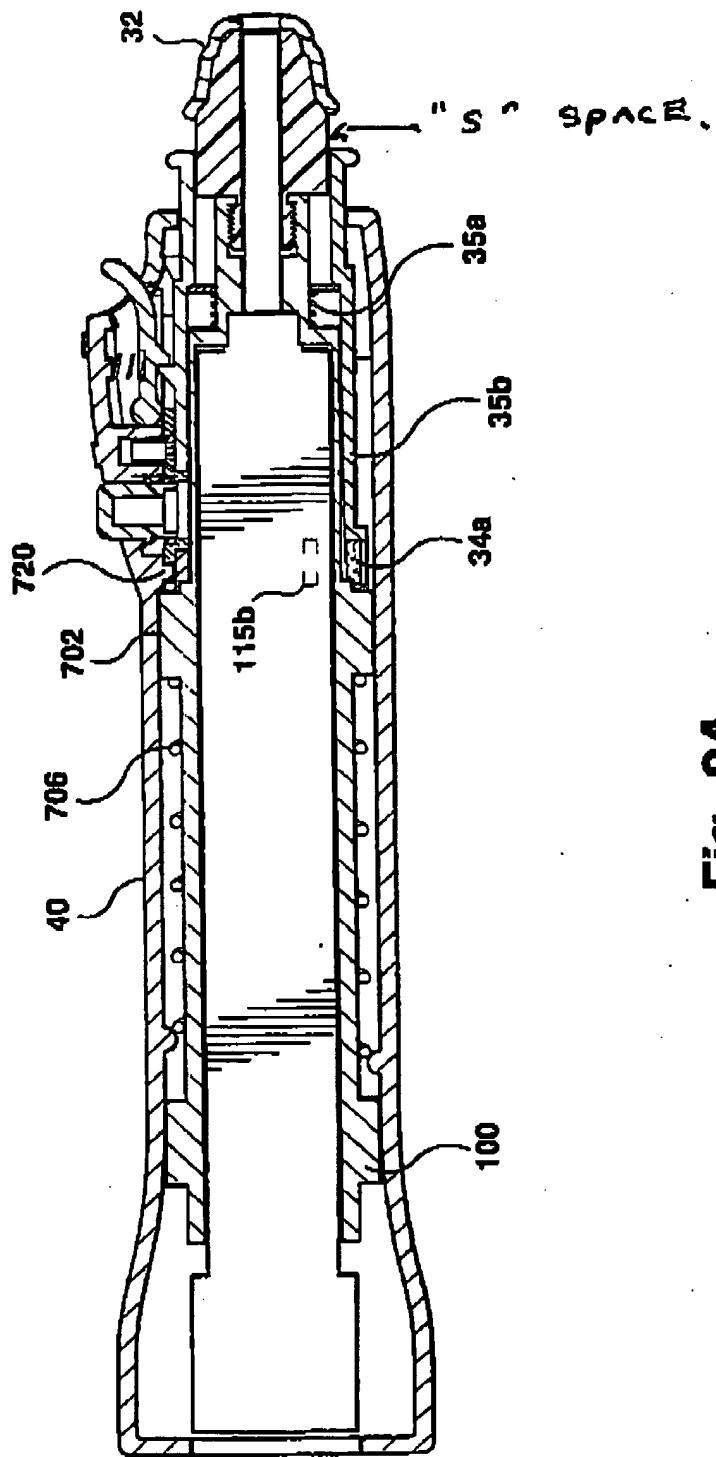


Fig. 8A

APPLICANT'S EXHIBIT I

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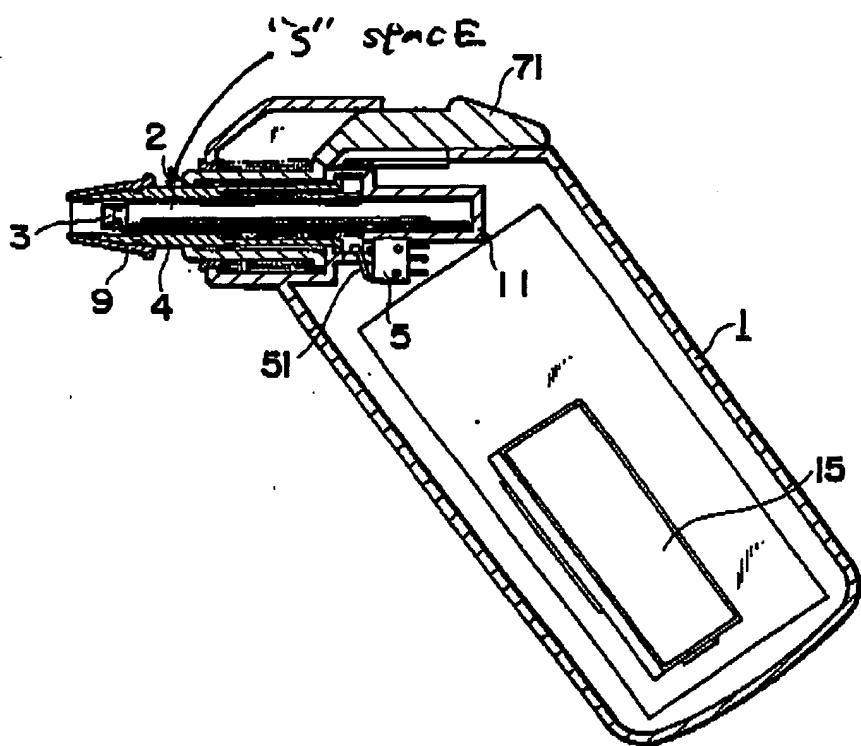
U.S. Patent

Aug. 23, 1994

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5,340,215

Fig. 1



January 23, 2008

Commissioner for Patents
Attention of Examiner Towa
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313

Dear Examiner:

I am a Registered Nurse and public health currently employed by the assignee of the Applicant. I have 9 years of experience in the areas of healthcare using these types of devices.

I have worked in the field of medical device technology for 4 years.

In Lantz (US Patent Application 2006/0120432A1), Figure 8, our probe cover 32 is flush with the distal end 24 of the thermometer 20. The cover 32 covers the heat sensing 22 probe tip shown in figure 10. As stated in paragraph 10, the cover is hygienic to provide a sanitary barrier. This barrier as shown in figure 8 covers the probe tip 22 during use. This prevents build up of patient discharge which may harbor infectious material/debris that can serve as a source for infection for the patient as well as a source for contamination of other patients. Fomites, or microbes on inanimate objects can be transferred from one patient to another, this is known as cross contamination.

At Sato (US Patent 3,738,173), figure 10 shows a probe cover 12. The probe cover is shown attached to the probe in Figure 4 and partially covers the collar 13. The collar 13 is exposed as shown at A-A'. This exposed area is shown between A-A' and is an area in which germs are deposited from a patient and allow for cross contamination.

At Makita (US Patent 5,340,215), figure 3 shows a probe cover 9. The probe cover is shown attached to a probe 3 and partially covers a probe tip 4. The tip is exposed as shown at B-B'. This exposed area is between B-B' and is an area in which germs are deposited from a patient and allow for cross contamination.

As noted above, the exposed area provides microbes and potential pathogenic microbes the opportunity to populate the device. In doing so, this can serve as a source of infection for the patients. Because one thermometer is used to serve many patients and only the probe covers are exchanged between patients, debris left behind harboring microbes can be carried and transmitted to other patients. This can be especially damaging to healthcare protocols that intend to contain the spread of infection.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,

Loredana Jinga SS 55W, MPA

Loredana Jinga, RN

Attachments

Affidavit Exhibits 1, 2, and 3.

Affidavit Exhibit 1.

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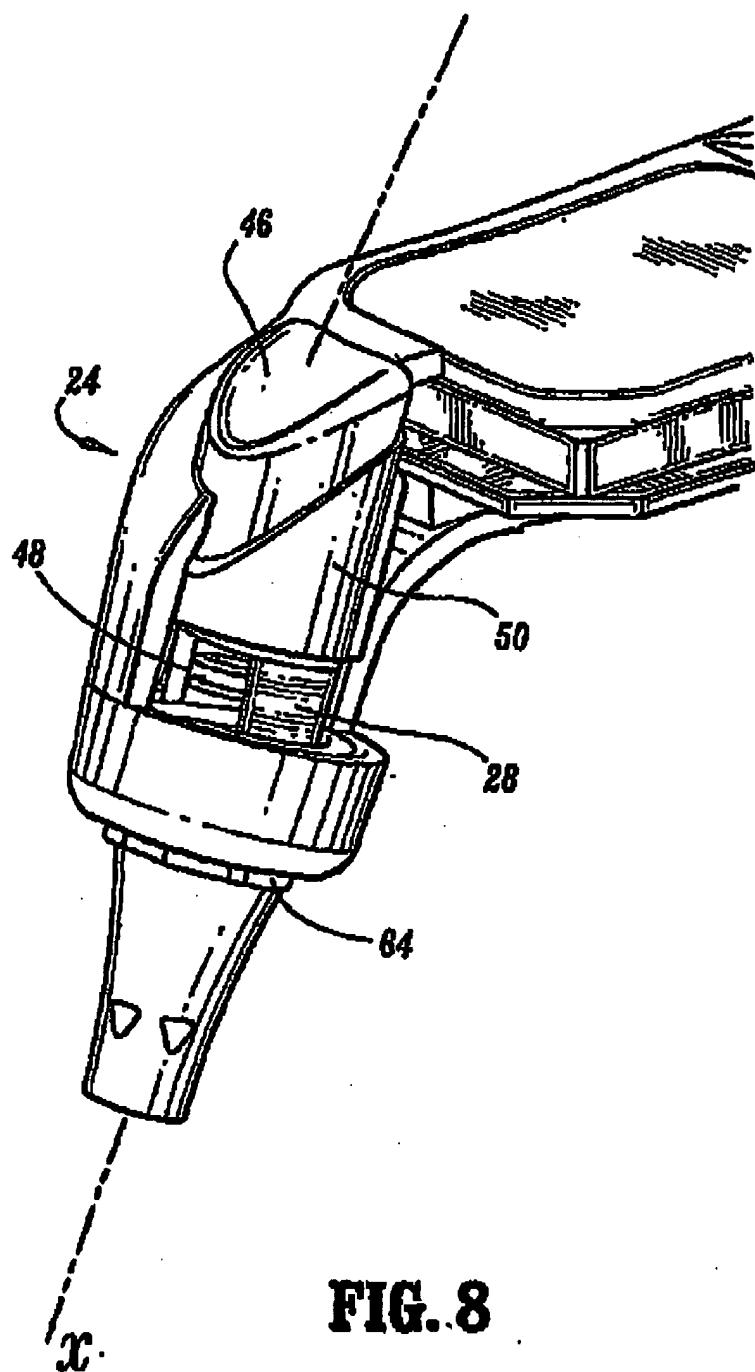


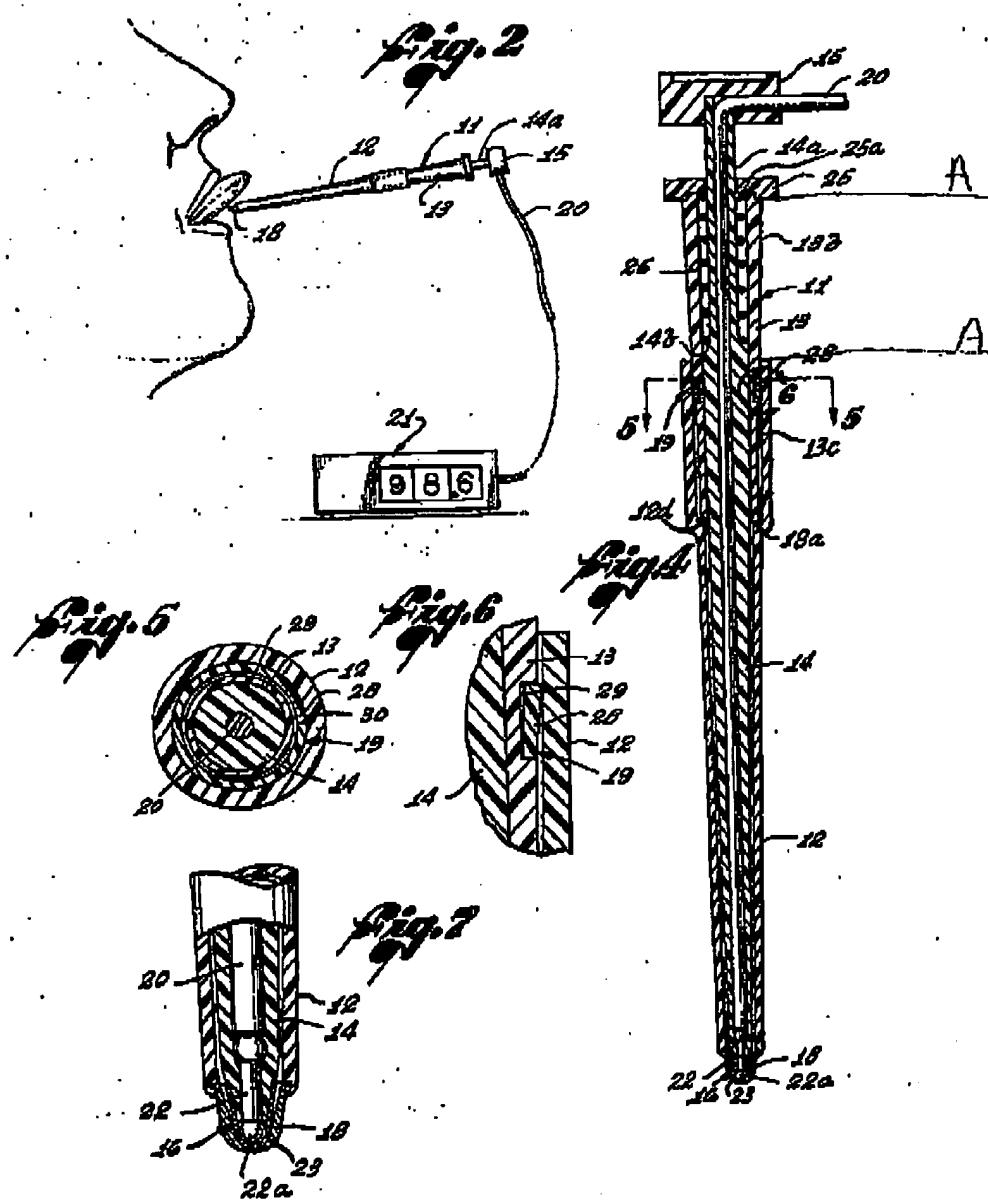
FIG. 8

Affidavit Exhibit 2

PATENTED JUN 12 1973

3,738,173

SHEET 2 OF 3



Affidavit Exhibit 3
U.S. Patent Aug. 23, 1994 Sheet 3 of 6 **5,340,215**

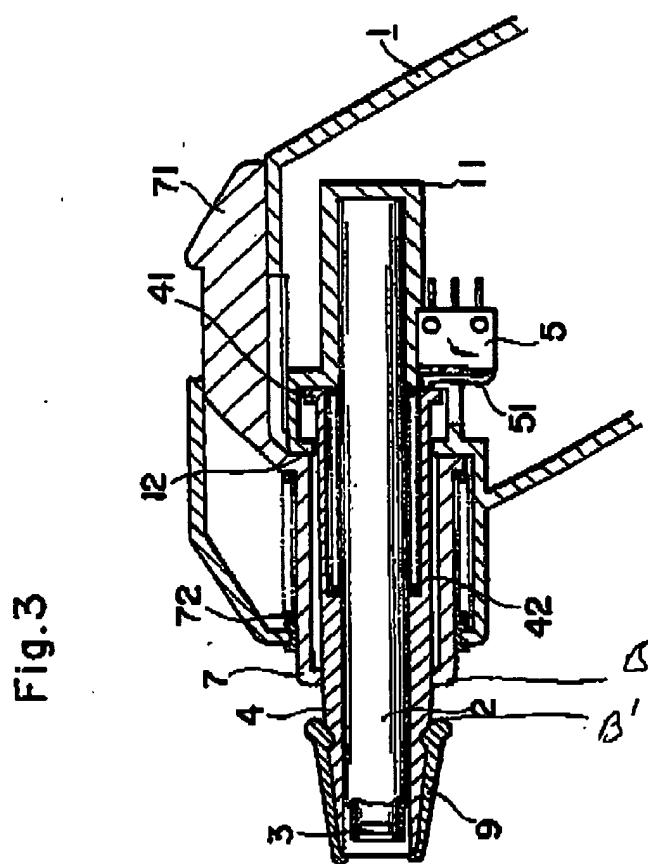


Fig. 3